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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/887,789 | 06/22/2001 | Michael P. Whitman | 11443/56 | 7650 |

110 7590 08/12/2003
DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
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EXAMINER

TRAN, LOUIS B

ART UNIT PAPER NUMBER

3721

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

NY

| | | | |
|------------------------------|-----------------|----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/887,789 | WHITMAN ET AL. | |
| | Examiner | Art Unit | |
| | Louis B Tran | 3721 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 June 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 6-32 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 6-32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| <ol style="list-style-type: none"> 1)<input type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | <ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: _____. |
|--|---|

DETAILED ACTION

This action is in response to applicant's amendment, Paper No. 13, received on 06/19/2003. Applicant's cancellation of claims 2-5 in Paper No. 13 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 32 recites the limitation "said first surgical device" in line 2 of the claim.

There is insufficient antecedent basis for this limitation in the claim. Claim 1 claims a surgical device but does not indicate if it is a first or second and claim 1 also recites "first surgical instrument". It is unclear what first surgical device is making reference to.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 6-8, 20-26, 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk (5,330,486).

With respect to claim 1, Wilk teaches the use of a surgical device comprising a hollow shaft 216 having a distal end at least a first rotatable drive shaft 220 disposed in the hollow shaft and extending longitudinally through the hollow shaft to the distal end of the hollow shaft and a first surgical instrument 222 configured to be detachably coupled to the drive shaft and the distal end of the hollow shaft wherein the hollow shaft is configured to be inserted into a body via a first orifice and the first surgical instrument is configured to be inserted into the body via a second orifice as seen in Figure 10 and wherein the hollow shaft and drive shaft are configured to be coupled to be coupled with the first surgical instrument after the hollow shaft is inserted into the body via the first orifice and after the first surgical instrument is inserted into the body via the second orifice as seen in Figure 10.

With respect to claim 6, Wilk teaches wherein the first surgical instrument includes a surgical stapler instrument.

With respect to claim 7, Wilk teaches wherein the first surgical instrument includes a surgical stapler and cutter instrument.

With respect to claim 8, Wilk teaches wherein the first surgical instrument includes an anastomosis instrument.

With respect to claim 20, Wilk teaches the steps of (a) inserting a hollow shaft having a distal end into the body via a first orifice, the hollow shaft containing a drive shaft rotatably disposed therein, (b) inserting a surgical instrument into the body via a second orifice, the surgical instrument including a coupling complimentary to and configured to couple with the distal end of said hollow shaft to connect the drive shaft

with the surgical instrument in operable communication and (c) coupling the hollow shaft and the surgical instrument via the coupling after the inserting steps (a) and (b) as seen in Figure 10 described in column 14, lines 15-45.

With respect to claim 21, Wilk teaches wherein the hollow shaft and the surgical instrument are coupled in the coupling step (c) intracorporeally.

With respect to claim 22, Wilk teaches the step of forming a surgical procedure after the coupling step (c) as described in column 14 lines 15-40.

With respect to claim 23 and 24, Wilk teaches wherein the surgical procedure includes a tissue stapling and cutting procedure.

With respect to claim 25, Wilk teaches wherein the surgical procedure includes an anastomosis procedure.

With respect to claim 26, Wilk teaches wherein the surgical instrument includes at least one of a surgical stapler instrument, a surgical stapler and cutter instrument and an anastomosis instrument.

In reference to claim 28, Wilk teaches wherein the first orifice includes at least one of a natural orifice, an incision, and a cannula.

In reference to claim 29, Wilk teaches wherein the second orifice includes at least one of a natural orifice, an incision, and a cannula.

In reference to claim 30, Wilk teaches wherein each of the first orifice and the second orifice includes at least one of a natural orifice, an incision and a cannula.

With respect to claim 31, Wilk teaches wherein the first orifice is different from the second orifice as seen in Figure 10.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,330,486) in view of Wilk (5,314,436).

With respect to claim 9 and 27, Wilk (486) discloses the invention substantially as claimed but does not show wherein the hollow shaft and the first surgical instrument coupled to the hollow shaft are configured to be withdrawn from the body via the first orifice.

However, Wilk (436) teaches wherein the hollow shaft and the first surgical instrument coupled to the hollow shaft are configured to be withdrawn from the body via the first orifice as described in column 4, lines 26-40 for the purpose of ease of removal as in column 1, lines 46-57.

Therefore, it would have been obvious to one having ordinary skill in the art to provide a modified method of removal in order to increase convenience.

8. Claims 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,330,486) in view of Adams et al. (6,119,913).

Wilk discloses the invention substantially as claimed including the above and generally shows wherein the first surgical instrument includes at least one movable

element but does not explicitly show the flexible shaft including at least one rotatable drive shaft configured to effect movement of the at least one movable element.

However, Adams et al. teaches the use of wherein the surgical instrument includes at least one movable element 20, a shaft including at least one rotatable drive shaft 24 configured to effect movement of the at least one movable element 20 (as in claim 10), a second rotatable drive shaft in the hollow shaft and wherein the first surgical instrument includes a first movable element 20 and a second movable element 36, and wherein the first rotatable drive shaft 22 is configured to effect movement of the first movable element and the second rotatable drive shaft 24 is configured to effect movement of the second movable element seen in Figure 5 (as in claim 14), wherein the elongated shaft includes a first coupling at the distal end and the first surgical instrument includes a second coupling for coupling with the first coupling of the elongated shaft and wherein a first coupling 717 and second coupling 719 are configured to couple the first movable element 20 and the first rotatable drive shaft 724' and to couple the second movable element with the second rotatable drive shaft 722' (as in claim 15), for the purpose of closing an anvil with a stapling portion as described in column 8, lines 5-25.

Adams et al. also teaches a device wherein the elongated shaft includes a first coupling at the distal end and the first surgical instrument includes a second coupling for coupling with the first coupling and wherein a first coupling (tip of 717) and second coupling 719 are configured to couple the at least one movable element 720 with the rotatable drive shaft 724' as described in column 10, line 12 for the purpose of

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connecting two ends (as in claim 11). Adams also teaches a device further comprising an electro mechanical driver device configured to drive at least one rotatable drive shaft (as in claim 12), wherein the electromechanical driver device includes a motor system configured to drive the at least one drive shaft (as in claim 13), and a device further comprising an electromechanical driver device configured to drive the first rotatable drive shaft and the second rotatable drive shaft as seen in Figure 1 (as in claim 16), wherein the electro mechanical driver device includes a motor system configured to drive the first rotatable drive shaft and the second rotatable drive shaft (as in claim 17), wherein the motor system includes a first motor configured to drive the first rotatable drive shaft and a second motor configured to drive the second rotatable drive shaft (as in claim 18) and wherein the hollow shaft includes a steering device 16 configured to steer the distal end of the hollow shaft (as in claim 19) all described in column 6, lines 35-37.

Therefore, it would have been obvious to one having ordinary skill in the art to provide Wilk with a rotatable closure element system in order to close an anvil for stapling.

9. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,330,486) in view of Mastri et al. (5,782,396).

Wilk discloses the invention substantially as claimed including a surgical device with a distal end and hollow shaft and drive shaft but does not explicitly show a second surgical device interchangeable with said first surgical device, said second surgical

device configured for selective attachment to the distal end of the hollow shaft and drive shaft to operably couple the second surgical device to said drive shaft.

However, Mastri et al. teaches the use of a second surgical device interchangeable with said first surgical device, said second surgical device configured for selective attachment to the distal end of the hollow shaft 14 and drive shaft 64 to operably couple the second surgical device to said drive shaft for convenient removal and changeability of parts as in column 5, lines 1-25.

Therefore, it would have been obvious to one having ordinary skill in the art to provide interchangeable feature as is commonly practiced in the art in order to provide convenient removal and changeability.

Conclusion

10. Applicant's remarks have been fully considered but are deemed moot in view of the new grounds of rejection.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis B Tran whose telephone number is 703-305-0611. The examiner can normally be reached on 8AM-6PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I Rada can be reached on 703-308-2187. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Ibt
August 7, 2003



Rinaldi I. Rada
Supervisory Patent Examiner
Group 3700